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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/558,474	04/25/00	BAZAN	J 15631-004810

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HM12/0629

EXAMINER

PRASAD, S

ART UNIT	PAPER NUMBER
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1646

DATE MAILED:

06/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/558,474

Applicant(s)

Bazan, J. Fernando

Examiner

Sarada C Prasad

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10 and 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Detailed Action

1. Receipt of pre-amendment in Paper No. 7 (9/5/00) is acknowledged. Original claims 1-17, and 11-20 have been cancelled, amendments to claims 8-9 have been entered, and new claims 21-28 have been added.
2. Currently, amended claims 8-9, original claim 10, and new claims 21-28 are under consideration by the Examiner.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- 3a. Claims 8-10, and 21-28 are rejected under 35 USC § 101 because they are drawn to an invention with no apparent or disclosed utility.

The instant application has provided a description of a mammalian interleukin IL-B30 and its possible biological activities. The breadth of its biological functions and possible uses have been disclosed in the specification, and they are largely dependent upon the structural homology of the instant IL-B30 to G-CSF and IL-6 (see specification page 4, second para, lines 1-3).

The instant invention lacks patentable utility because the phenomena of the IL-B30 molecule binding to its receptor and transduction of the signal for the claimed effectiveness and functionality of the IL-B30 are hypothetical. It is clear from the instant specification that the protein IL-B30 of SEQ ID No. 2 encoded by the nucleic acid of SEQ ID NO: 1 is a homologue of IL-6 and G-CSF. There is little doubt that, after further characterization, this protein will

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probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claim of therapeutic utility as a novel cytokine is incomplete.

The instant situation is analogous to that which was addressed in *Brenner v Manson*, 148 USPQ 689 (SUS. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which are known to possess anticancer activity was alleged to be a potential antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 USC 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-here is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and a "patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to polynucleotides encoding polypeptides like cytokines of known function based on homology, however, as of yet not shown to have their own identity by way of demonstrated biological effects or functions. Until some actual and specific significance can be attributed to the IL-B30 polypeptides and the nucleic acids encoding them (SEQ ID Nos. 1 and 3), the instant invention is incomplete. In the absence of knowledge of the biological significance of these proteins, there are no immediately obvious patentable uses for these IL-B30-like homologues. Since the instant invention does not disclose a "real world" use for the nucleic acids of SEQ ID NOs. 1 and 3, the claimed invention is incomplete, and therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claims 8-10, and 21-28 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112-second para

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8-10 and 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claims 8 and 9 recite 'wash conditions of at least 65⁰C' which is a conditional limitation, and the conditions that are recited in the claim are not clear rendering the claims indefinite. The phrase 'at least 65⁰ C', does not convey how low or how high the hybridization temperature can be. Thus, the metes and bounds of the claim can not be ascertained and it is not clear if the temperature of the wash buffer is 62⁰C, 64⁰C, or 68⁰C. This rejection can be obviated by supplying the specific and appropriate wash conditions supported by the specification, such that more perfect matches are obtained.

4b. Claims 8 and 9 recite 'less than about 150 mM salt' as a conditional limitation for post hybridization wash conditions. As set forth in paragraph 4a, both temperature and concentration of salt determine the stringency of the wash condition and specificity of hybridization. Thus, recitation of 'about 150 mM' salt makes it confusing as to what is the salt concentration that can be employed for the probe hybridization, is it 100 mM, or 120 mM? Thus, the metes and bounds of the claims can not be ascertained. This rejection can be obviated by supplying the specific salt concentration in the washing solutions, supported by the specification, which Applicant considers are of appropriate stringency for wash subsequent to hybridization such that more perfect matches are obtained. Claim 10 is rejected insofar as it depends on claim 9.

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4c. Claims 21-28 recite 'said probe hybridizes to at least XX (25 or 35 or 55 or 60) nucleotides of said open reading frame of SEQ ID No. 1 or said open reading frame of SEQ ID No. 3'. The phrase 'at least 25 nucleotides' fails to set forth the limitation that the stretch of nucleotides forming the duplex should be 'contiguous'. This rejection can be obviated by reciting 'hybridizing to at least XX contiguous nucleotides...'.

Conclusion

5. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday - Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.
Examiner
Art Unit 1646
June 25th, 2001

Panna Mertz
PREMA MERTZ
PRIMARY EXAMINER